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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,055	09/25/2006	Susanne Busch	2923-779	8810
6449 7590 06/18/2010 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT		PAPER NUMBER		
1612				
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06/18/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/594,055

Applicant(s)

BUSCH ET AL.

Examiner

Snigdha Maewall

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-54 is/are pending in the application.
- 4a) Of the above claim(s) 53 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Summary

1. Receipt of IDS filed on 09/25/06 is acknowledged.

Restriction/Election

Claims 1-28 have been cancelled, new claims 29-54 have been added.

Applicant's election of group IV, claims drawn to a composition comprising an a) alkaline medium, b) first gel with gelatin and phosphate ions c2) with a medium containing calcium ions, in the reply filed on 03/30/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). New claims 29-52, which are directed to the elected invention are included in the prosecution. Applicant's election of second gel being free of phosphate ions and alkaline solution is also acknowledged.

Claims **53-54** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/30/10. Claims 53-54 are not included in the prosecution for being drawn to non elected invention.

Accordingly, claims **29-52** are under prosecution.

Information Disclosure Statement

The information disclosure statement filed November 24, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Copies have not been received.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 29-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 29 recites the limitation as a first gel with phosphate ions in subsection (b) and dependent claim 30 recites presence of calcium phosphate in first gel. Claim 29 also recites a medium containing calcium ions in subsection (c). It is not clear how the medium, in the absence of any specifically defined medium (gel or solution), be different from second composition comprising calcium ions. Further more, if the alkaline medium in claim 29 is intended to be gel, then it is unclear how the three subsections are

different from one another, because a gel comprising calcium and phosphate and gelatin will read on single composition which is not the case as described in instant specification, Thus claims are ambiguous and not distinctly claim the subject of invention. The metes and bounds of alkaline medium in claim 29 is not clear, it is not clear which alkaline component is the applicant referring to. Since the calcium containing medium can be interpreted as alkaline due to basic nature of calcium, the difference in pH between alkaline medium claimed subsection a and c are not clear. The claims are thus indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 29, 36-38 and 48- 52 are rejected under 35 U.S.C. 102(b) as being

anticipated by Raaf et al. (US 4,397,837).

Raaf et al. disclose two-part compositions, one comprising a soluble calcium and the second comprising a soluble phosphate. The compositions are for the remineralization or inhibiting demineralization of teeth. Demineralization is when the apatite crystals are degraded (col. 1, lines 27-28). Therefore it appears the compositions form apatite crystals on the teeth. Each part is added to the teeth in sequential order. The compositions may be in the form of a paste, **a gel, or a solution** (col. 2, lines 43-44). The gels include known thickeners (col. 4, line 13). An example of a thickener used in the compositions is carboxymethylcelluloses and caragheenate (see examples). The compositions also comprise glycerol (see examples). The compositions also comprise fluoride in the phosphate comprising part and comprise no fluoride in the calcium containing part. Gelatin was used in the compositions disclosed by the examples and is a thickening agent¹. The calcium compounds are Another embodiment of the inventions is to provide more than two layers wherein the third layer optionally comprises a fluoride component (col. 6, lines 3-10). It is concluded that the layer may be free of fluoride encompassing claims 5, 20 and 27. The phosphate and calcium phases are separated during storage containers such as two-component tubes and can be kept separate and dispensed separately from one another. The reference discloses calcium ions containing medium which can be interpreted as an alkaline medium since it has alkali salt in it, additionally, since the claims do not define specific alkaline medium, the medium containing calcium will read on the alkaline medium. The

pH of the alkaline medium is although not disclosed in the reference, however, it can be inferred that the medium comprising calcium will be considered to possess the claimed pH which is from 6 to 8 because of calcium ions which are basic in nature absent evidence to contrary.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raaf et al. (US 4,397,837) in view of DiGiulio et al. USP 4,080,440.

Raaf et al. disclose two-part compositions, one comprising a soluble calcium and the second comprising a soluble phosphate. The compositions are for the remineralization or inhibiting demineralization of teeth. Demineralization is when the apatite crystals are degraded (col. 1, lines 27-28). Therefore it appears the compositions form apatite crystals on the teeth. Each part is added to the teeth in sequential order. The compositions may be in the form of a paste, **a gel**, or **a solution** (col. 2, lines 43-44). The gels include known thickeners (col. 4, line 13). An example of a thickener used in the compositions is carboxymethylcelluloses and caragheenate (see

¹ Gaffar et al. (US 4,474,750) col. 5, lines 10-21).

examples). The compositions also comprise glycerol (see examples). The compositions also comprise fluoride in the phosphate comprising part and comprise no fluoride in the calcium containing part. Gelatin was used in the compositions disclosed by the examples and is a thickening agent². Another embodiment of the inventions is to provide more than two layers wherein the third layer optionally comprises a fluoride component (col. 6, lines 3-10). It is concluded that the layer may be free of fluoride. The phosphate and calcium phases are separated during storage containers such as two-component tubes and can be kept separate and dispensed separately from one another.

The reference differs from the instant claims insofar as it does not disclose the multi-part compositions are gels with one gel comprising phosphate ions, a second gel medium comprising calcium ions but the compositions may be in the form of gels.

The reference is not anticipatory insofar as one must "pick and choose" from different lists of forms of compositions and whether the compositions are two or more phases. That being said, it would have been obvious in a self-evident manner to have selected gels from one list and a three gel system from another, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners.

² Gaffar et al. (US 4,474,750) col. 5, lines 10-21).

The reference discloses calcium ions containing medium which can be interpreted as an alkaline medium since it has alkali salt in it, however, specific mention of alkaline medium is missing from the reference.

DiGiulio et al. discloses that use of slightly alkaline supersaturated calcium phosphate solutions effect some degree of enamel remineralization, see column 1, lines 45-48. Example 1 teaches utilizing alkaline NaOH 10 % solution in tooth paste preparation in column 8.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an alkaline medium comprising calcium ions into the apatite forming composition of Raaf et al. in order to effect better and effective remineralization that is apatite formation.

9. Claims 38 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raaf et al. (US 4,397,837) in view of Wiedemann (US 6,010,684).

Raaf et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the pH of the compositions.

Wiedemann discloses two part compositions comprising in one-part phosphate ions and in the second calcium ions for the remineralization of teeth (col. 1, lines 11-20). The phosphate compositions have a pH of 3.0 to 6.5 and the calcium compositions have a pH from 3.0 to 7.0 encompassing claims 38 and 51. The compositions may also comprise fluoride ions in the phosphate comprising composition. The resulting mixture should yield a pH from 2.0 to 5.0 (col. 1, lines 59-67). The pH remineralization of the

teeth is dependent on the pH of the compositions and results in a deep remineralization effect.

It would have been obvious to one of ordinary skill in the art to have adjusted the pH of each gel of the primary reference motivated by the desire to obtain the deep remineralization effects when the phosphate is reacted with calcium as disclosed by the secondary reference.

10. Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raaf et al. (US 4,397,837) in view of Barth et al. (US PG pub. 20070154411).

Raaf et al. as discussed above do not disclose fluoroapatite or particle size. Barth et al. teaches utilization of fluoroapatite, hydroxyapatite, calcium hydrogen phosphate and calcium fluoride as remineralization –promoting agent and the amount to be added in the composition is from 0.1 to 10% by weight, see [0062] and [0061]. The particle size is disclosed to be from 1 to 200 microns in [0042].

It would have been obvious to one of ordinary skill in the art to have utilized the remineralization –promoting components such as fluoroapatite in the compositions of Raaf et al. for promoting better remineralization because Raaf teaches utilization of calcium salts for apatite formation and '411 teaches the specific calcium salts for the same cause that is dental remineralization. Optimization of particle would be obvious to one of ordinary skill in the art in order to achieve optimum results absent evidence of unexpected results with the claimed sizes.

11. Claims 29, 30-38 and 48- 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebner (DE 33 03 937 Translation) in view of Singh et al. (US 2003/0152528) and further in view of DiGiulio et al. USP 4,080,440.

Ebner discloses gel compositions comprising phosphate gelatinized solutions and calcium gelatinized solutions. The method includes applying a phosphate salt to the teeth with a cap followed by the application of a calcium salt with a cap or vice versa. Gelatin is used as the gelatinizing agent. A fluoride source is also incorporated into the phosphate compositions. Additional agents such as anti-bacterial agents and whitening agents may also be included in one of the caps (page 7). The reference differs from the instant claims insofar as it does not disclose a second gel that is absent of phosphate or fluoride ions.

Singh et al. disclose hydrogel compositions for whitening teeth. The reference is used as a general teaching to show active ingredients may be separated into different layers depending on their reactivity to one another. The hydrogels may have one or more additional hydrogel or non-hydrogel layers comprising additives that are not compatible with the whitening agent (paragraph 0116).

It would have been obvious to one of ordinary skill in the art to have used a three gel system in forming the calcium phosphate layer on the teeth disclosed by the primary reference motivated by the desire to inhibit the phosphate or calcium ion from possibly reacting with additional additives as disclosed by the secondary reference.

The references discussed above disclose calcium ions containing medium which can be interpreted as an alkaline medium since it has calcium salt in it, however, specific mention of alkaline medium is missing from the reference.

DiGiulio et al. discloses that the use of slightly alkaline supersaturated calcium phosphate solutions effect some degree of enamel remineralization, see column 1, lines 45-48. Example 1 teaches utilizing alkaline NaOH 10 % solution in tooth paste preparation in column 8.

Thus, it would have been obvious too ne of ordinary skill in the art at the time the invention was made to incorporate an alkaline medium comprising calcium ions into the apatite forming composition of Raaf et al. in order to effect better and effective remineralization that is apatite formation.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612